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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,166	07/09/2003	Rourke M. Yeakley	YEAR102	2728

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EXAMINER	
KEASEL, ERIC S	
ART UNIT	PAPER NUMBER
3753	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/617,166	YEAKLEY, ROURKE M.	
	Examiner	Art Unit	
	Eric Keasel	3753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6-11 and 14-17* is/are pending in the application.

4a) Of the above claim(s) *17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-11 and 14-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *7/9/03&10/3/06* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in the reply filed on January 9, 2006 is acknowledged.

2. Claim 17 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 9, 2006.

Drawings

3. The drawings were received on October 3, 2006. These drawings are not accepted. The proposed drawings have an additional leader line from a new reference number 50 pointing to the medication in a dry, powdered form (Fig. 1A) or in combination with a reconstituting liquid (Fig. 1B). This appears to introduce new matter as the medication in a dry, powdered form or in combination with a reconstituting liquid is not an expelling material.

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the squeezable propellant chamber and the expelling material must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure

must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. The disclosure is objected to because reference number "50" should be removed from the specification because the drawings of record do not have a reference number 50. Appropriate correction is required.

6. The declarations under 37 CFR 1.132 filed June 30, 2006 are insufficient to overcome the rejection of any of the claims based upon the rejections of record as set forth in the last Office action because

The declarations fail to establish that the device alleged to provide the commercial success/long felt need is the claimed invention of the instant application. Declarations not relating to the specifics of the claimed invention are not persuasive. Evidence of commercial success/long felt need must be commensurate in scope with the scope of the claims.

The declarations, as they pertain to long felt need, fail to establish if other attempts to improve on or solve problems with plastic roller type pinch assemblies, if any, were made. Further, if other attempts have been made, what were they, and were such failures due to lack of

interest or appreciation of an invention's potential or marketability rather than want of technical know-how, etc.

The declarations must set forth facts, not mere conclusions, and the facts must be pertinent to the rejection. The declarations fail to address the amount and nature of the evidence submitted. In fact, there appears to be no evidence submitted. The declarations also fail to address whether the letters were solicited or voluntarily submitted absent any incentive.

Therefore, having considered the factual inquiries specified in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), and the factual allegations in the applicant's declaration in accordance with the provision of 37 CFR 1.132, the rejections are deemed proper for the reasons set forth in the rejection of April 4, 2006.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-3, 6-11, and 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "an opening in said ampule" in line 6 and also recites "to create an opening of a desired size within said ampule" in lines 8 and 9. It is unclear if these recitations are meant to refer to the same openings or two different openings.

Claim 9 recites "an opening of a calibrated size" in lines 11 and 12 and also recites "to produce a hole of a calibrated size within said ampule" in lines 14 and 15. It is unclear if these

recitations are meant to refer to the same opening or hole or if an opening is different from a hole.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-3, 6-11, and 14-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites "an opening in said ampule" in line 6 and also recites "to create an opening of a desired size within said ampule" in lines 8 and 9. If the recitations are meant to refer to two different openings, then the claimed subject matter was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 2 recites that the ampule is "laterally" compressed. The originally filed specification is silent as to the direction of any compression. Therefore, the claimed subject matter was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 9 recites "an opening of a calibrated size" in lines 11 and 12 and also recites "to produce a hole of a calibrated size within said ampule" in lines 14 and 15. It is unclear if these

recitations are meant to refer to the same opening or hole or two different openings (or holes). If the recitations are meant to refer to an opening and a different hole, then the claimed subject matter was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

11. In light of the above informalities, the claims have been examined as could best be understood by the examiner. The examiner's failure to apply prior art to any of the claims should not be construed as an indication of allowable subject matter.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-3, 6, 7, 9-11, 14, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Mukasa et al. (US Patent Number 6,386,872).

Mukasa et al. disclose a self-contained dispensing system for dispensing measured amounts of medication stored in a powdered form (A) comprising: an ampule (see generally at Fig. 1) having a first chamber (1a) configured to hold a premeasured amount of a selected medication stored in a powdered form (A) therein, and a second chamber (2a) configured to hold a premeasured amount of a reconstituting liquid (B) therein, said first chamber separated from said second chamber by a breakable membrane (2c), said ampule configured to allow an individual to break said membrane to suspend said powder within said reconstituting liquid and

to allow said suspension to be dispensed from said ampule through an opening (1c, 4a) in said ampule when pressure is applied to said ampule; wherein said ampule further comprises a squeezable propellant chamber (i.e. plunger 3 is squeezed into cylinder 2), said propellant chamber configured to contain a designated quantity of an expelling material (including air), said propellant chamber configured to compress when a designated quantity of pressure is applied to said propellant chamber and to force said expelling material and said medication out of said ampule; further comprising a puncturing device (3a) configured to create said opening within said ampule; wherein said puncturing device is calibrated to create an opening of a desired size within said ampule (at least as calibrated as applicant's puncturing device is calibrated); further comprising a container configured to hold said ampule and said puncturing device, in a sealed environment (see generally at Fig. 1, the entire device is a sealed container); and wherein said puncturing device is a portion of said container.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 1-3, 5, 6, 9-11, 14, and 15 (as understood) are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeberg et al. (US Patent Number 3,327,710).

Freeberg et al. disclose a self-contained dispensing system for dispensing measured amounts of medication stored in a powdered form (22) comprising: an ampule (see generally at Fig. 1) having a first chamber (21) configured to hold a premeasured amount of a selected

medication stored in a powdered form (22) therein, and a second chamber (28) configured to hold a premeasured amount of a reconstituting liquid (29) therein, said first chamber separated from said second chamber by a breakable membrane (36), said ampule configured to allow an individual to break said membrane to suspend said powder within said reconstituting liquid and to allow said suspension to be dispensed from said ampule through an opening (in 19) in said ampule when pressure is applied to said ampule; wherein said ampule further comprises a squeezable propellant chamber (i.e. plunger 18 is squeezed into cylinder 13), said propellant chamber configured to contain a designated quantity of an expelling material (including air), said propellant chamber configured to compress when a designated quantity of pressure is applied to said propellant chamber and to force said expelling material and said medication out of said ampule; further comprising a puncturing device (40) configured to create said opening within said ampule; wherein said puncturing device is calibrated to create an opening of a desired size within said ampule (at least as calibrated as applicant's puncturing device is calibrated); further comprising a container configured to hold said ampule and said puncturing device, in a sealed environment (see generally at Fig. 1; the entire device is a sealed container); and wherein said puncturing device is a portion of said container.

Freeberg et al. fail to disclose an oral liquid medication. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have used an oral liquid medication because applicant has not disclosed that the particular form of medication provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with any various other

medications because applicant specifically disclosed this in the application on page 10, paragraph 0025:

"Typically, this system is utilized with oral drug delivery, however it is to be distinctly understood that this disclosure is not limited thereto but may also be utilized with other types of drug delivery products."

Therefore, it would have been an obvious matter of design choice to modify Freeberg et al. to obtain the invention as specified in claims 1-3, 5, 6, 9-11, 14, and 15.

16. Claims 6, 8, 14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeberg et al. in view of Schmid (US Patent Number 5,819,921).

In an alternate reading of the Freeberg et al. reference, they fail to disclose a separate container (generally rectangular), with a bottom portion of the container configured to contain the puncturing device. Schmid discloses a similar ampule that rests in the bottom of a generally rectangular container (see Fig. 4). It would have been obvious to one having ordinary skill in the art to have placed the ampule (including the puncturing device) of Freeberg et al. in the container of Schmid in order to create a package that can be sterilized as a unit as taught by Schmid.

17. Claims 6, 8, 14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mukasa et al. in view of Discko, Jr. (US Patent Number 5,199,567).

In an alternate reading of the Mukasa et al. reference, they fail to disclose a separate container (generally rectangular), with a bottom portion of the container configured to contain the puncturing device. Discko, Jr. discloses a similar ampule that rests in the bottom of a generally rectangular container (see Fig. 1). It would have been obvious to one having ordinary skill in the art to have placed the ampule (including the puncturing device) of Mukasa et al. in

the container of Discko, Jr. so that the rectangular trays can be incorporated into a rack system as taught by Discko, Jr.

18. Claims 1-3 (as understood) are rejected under 35 U.S.C. 103(a) as being unpatentable over Fletcher et al. (US Patent Number 5,609,581).

Fletcher et al. disclose the invention recited in claims 1-3 except Fletcher et al. disclose the use with a topical medication as opposed to the recited oral liquid medication. Fletcher et al. fail to disclose an oral liquid medication. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have used an oral liquid medication because applicant has not disclosed that the particular form of medication provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with any various other medications because applicant specifically disclosed this in the application on page 10, paragraph 0025 and on page 5, paragraph 0011:

"Typically, this system is utilized with oral drug delivery, however it is to be distinctly understood that this disclosure is not limited thereto but may also be utilized with other types of drug delivery products."

"This dispensing system provides a variety of advantages over the prior art and provides a system for long-term storage of dosing medications, particularly oral and topical medications that can be utilized in a broad variety of circumstances by individuals with little or no medical training and which will provide safe, effective use of the medication which will thus provide designated healing properties."

Therefore, it would have been an obvious matter of design choice to modify Fletcher et al. to obtain the invention as specified in claims 1-3.

Response to Arguments

19. Applicant's arguments filed October 3, 2006 have been fully considered but they are either not persuasive or moot in view of the new grounds of rejection.

Applicant argues that amending the claims to recite a liquid, oral medication defines over the prior art. The examiner disagrees. Dental restoration material is a medicament (i.e. a substance used in therapy) that is dispensed in the liquid form (it must be liquid or it would not dispense even though it will later set) and is administered orally (the teeth are in the mouth). So, Mukasa et al. still anticipates some claims. However, applicant has gone out of their way in the specification to indicate that nature of what is dispensed is not to be limited to oral drug delivery. Please note the application on page 10, paragraph 0025 and on page 5, paragraph 0011:

"Typically, this system is utilized with oral drug delivery, however it is to be distinctly understood that this disclosure is not limited thereto but may also be utilized with other types of drug delivery products."

"This dispensing system provides a variety of advantages over the prior art and provides a system for long-term storage of dosing medications, particularly oral and topical medications that can be utilized in a broad variety of circumstances by individuals with little or no medical training and which will provide safe, effective use of the medication which will thus provide designated healing properties."

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. Any inquiry concerning this communication should be directed to Eric Keasel at telephone number (571) 272-4929, who can normally be reached Monday-Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Eric Keasel

ERIC KEASEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

Replacement Sheet

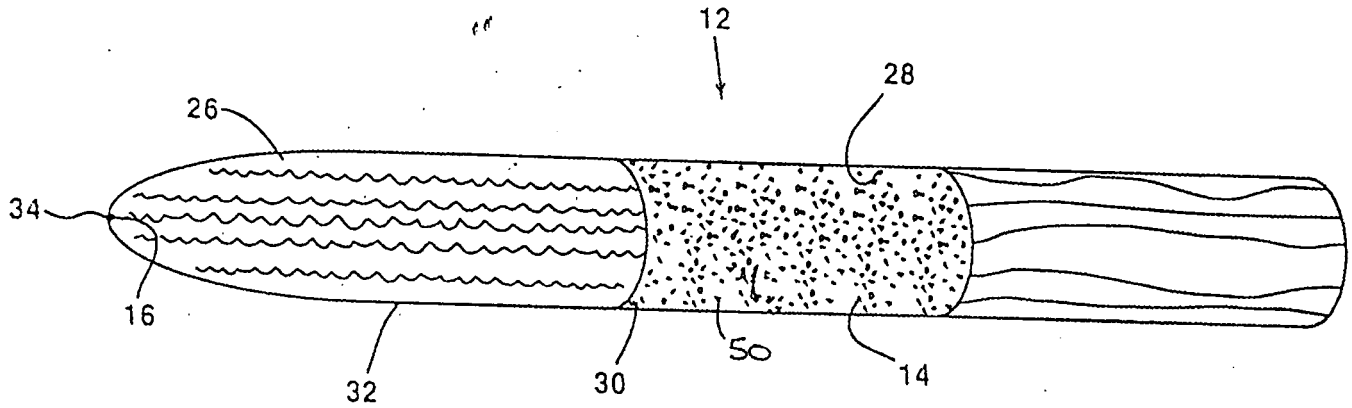

FIG. 1A

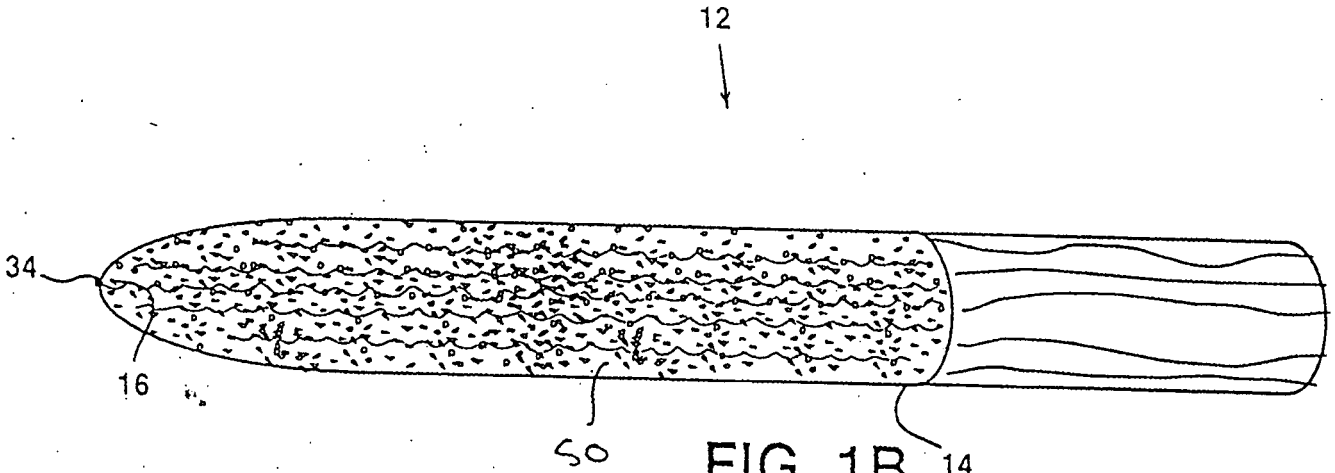

FIG. 1B

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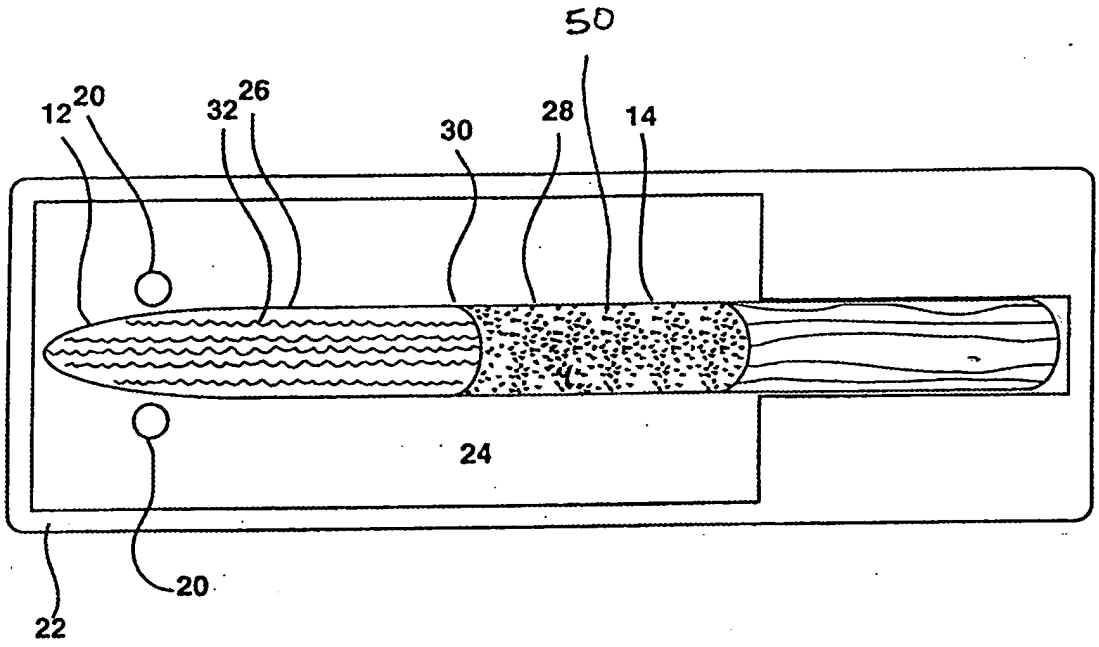

FIG. 4

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